

REMARKS

Claims 2-6, 8, 9, 11, 13, 14, 16-19, 21, 22, 24, 31-33, 35, 36 and 73-76 remain in this application. In the interests of furthering the present application to allowance, claims 8, 31, 73, and 75 have been amended, without prejudice, to (i) replace “comprising” with the words “consisting essentially of” as in the original claims (e.g., to remove the amendment made to the claims in the previous amendment) and (ii) to clarify that the second coating layer does not retard the dissolution of the active ingredient. Support for such amendment can be found throughout the specification, e.g., page 8, lines 23-25. Accordingly, no issues of new matter are believed to be raised by the above amendments to the claims. Applicants reserve the right to pursue the original claim scope in subsequent continuation/divisional patent applications.

I

The Rejection of Claims 2, 4-6, 8-9, 11, 13-14, 16-19, 21-22, 24, 31, 33, 35-36, and 73 were rejected under 35 USC §103(a) as Unpatentable Over Cherukuri et al. (EP 0,458,751) in view of Kanai et al. (US 4,868,183) and Uchida et al. (US 5,215,999) Should be Withdrawn

Claims 2, 4-6, 8-9, 11, 13-14, 16-19, 21-22, 24, 31, 33, 35-36, and 73 remain rejected under 35 USC §103(a) as unpatentable over Cherukuri et al. (EP 0,458,751) in view of Kanai et al. (US 4,868,183) and Uchida et al. (US 5,215,999). Applicants respectfully disagree for the reasons that follow.

According to the Office Action,

“Cherukuri et al teach a delivery system for a cyclic amino acid compound which offers reduced bitterness and improved mouthfeel with desired high temperature stability. Cherukuri et al. teach the delivery system comprises (a) a core material . . . (b) a first polymeric coating selected from water insoluble material . . . , and (c) a second hydrophobic coating selected from the group consisting of fats, waxes, and mixture. . . . Cherukuri et al. does not teach the second coating layer is comprises of a water soluble and/or water swellable film forming polymer and an anti-grit agent such as polyethylene oxide or polyethylene glycol or the claimed ratios. It is for this reason Kanai et al. and Uchida et al. are added as secondary references.”

See pages 3-5 of the Office Action. In addressing the teachings of Kanai et al. and Uchida et al., the Office Action states:

Kanai et al teach the resulting tablets were coated with a film coating agent consisting of hydroxypropyl methyl cellulose . . . , polyethylene glycol 6000 . . . , castor oil and ethanol, giving film coated tablets of the composition Uchida et al. further teach the tablets thus obtained were coated with a film comprising hydroxymethyl cellulose . . . , polyethylene glycol 6000 . . . , castor oil and methanol to prepare film-coated tablets. . . . Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element on the invention has been fairly suggested by the cited reference. (emphasis added).

See pages 5-7 of the Office Action.

Applicants again respectfully disagree. As previously argued in the prior response filed March 17, 2010 (“Prior Response”), Applicants assert that the current claims relate to coated particles, not to a coated tablet. As emphasized above, both Kanai et al. and Uchida et al. teach the use of the recited coatings in tablet coatings, not particle coatings as recited in the pending claims. As discussed in the Background of the Invention section, Applicants explain the need for texture of the drug-containing particles, especially in chewable tablets where any tablet coating would be broken upon chewing. Merely coating the outside of the tablets would not remove the gritty, sandy texture of the resulting particles after the tablet is chewed and the outside tablet coating is broken. Neither, Kanai et al. and Uchida et al. disclose or suggest the current claimed coated particles or methods of manufacturing coated particles.

In response to these arguments, the Office Action asserts that Cherukuri et al.

“teach active ingredient particles that are coated with two layers, a water insoluble polymer and a water soluble polymer. One skilled in the art at the time the invention was made would have motivated to use a water soluble polymer such as hydroxypropyl methyl cellulose and an anti-grit agent such as polyethylene glycol as the second coating in the formulations taught by the primary references because Kanai et al. and Uchida et al. teach these ingredients are used to prepare film-coated tablets. While, tablets are not particles, the technology of film coating particle or tablets with the same compounds or combinations of compounds is well known and documented in the art. As such, the skilled artisan would have been motivated to try a film-coating formulation that is well-known in the art, especially when the ingredients of the film-coating formulation can be used to prepare the coating layers used in the formulations taught by. . . Cherukuri et al. . . .”

See pages 11-12 of the Office Action.

The Office Action, however, fails to provide support for its assertion that ordinary skill in the art would look to use a film coating formulation intended for a tablet coating to coat particles merely because the technology of filming coating particles and tablets are similar. Further, both Kanai et al and Uchida et al. are silent to chewable tablets, so one of ordinary skill in the art would not look to these references for texture coating particles as with the pending claims.

While the applicants respectfully disagree, in the interests of furthering this application to allowance, have amended independent claims 8, 31, 73, and 75 to now recite that the second coating layer does not retard the dissolution of the active ingredient (e.g., because of the use of the water soluble and/or water swellable film forming polymer). Thus, this second coating layer recited in the pending claims is not hydrophobic as required by Cherukuri et al (e.g., soybean oil as in Examples 1 and 2). Further, there is no teaching or suggesting in Cherukuri et al. or either Kanai et al. or Uchida et al. to replace the required “second hydrophobic coating” of Cherukuri et al. with the second coating of the pending claims. One of ordinary skill in the art would not be motivated to replace the hydrophobic layer of Cherukuri et al. with a hydrophilic layer, as in the present claims, as this may modify the release of the drug from the particle.

Further, as recited in Example 4 of the present application, the application of this second water-soluble layer were unexpectedly found to improve the resulting particles, as compared to the particles with only the taste-masking layer, when used in a chewable tablet. As recited in Example 4, “[b]oth tablets were found to have had a similar taste, with a very slight bitterness detected by most panelists. The tablets from Example 1 [e.g., tablets made without the water-soluble layer] were found to have had a perceptible grittiness, which ranged from ‘slight’ to ‘obvious,’ and a rough surface. By contrast, the ‘texture-masked’ particles of the present invention produced in accordance with Example 3 were found to have had no grittiness, a smooth texture and a ‘good melt-away,’ i.e. the tablet was rapidly cleared from the oral cavity with minimal chewing required.” Further the use of layer was not found to retard the dissolution of the active ingredient as “100% of the acetaminophen active ingredient was released from the tablets of Example 1 and Example 3 in 45 minutes.” Such an unexpected result was not taught, nor suggested, by Cherukuri et al. nor by Kanai et al or Uchida et al.

Accordingly, Applicants assert that the presently claimed invention would not have been obvious to a person of ordinary skill in the art at the time of the claims invention was made in

light of these references. Thus, Applicants respectfully request that this rejection under 35 USC 103(a) be withdrawn.

II

The Rejection of Claims 2, 4-6, 8-9, 11, 13-14, 16-19, 21-22, 24, 31, 33, 35-36, and 73-76 were rejected under 35 USC §103(a) as Unpatentable Over CA 2,068,366 in view of Kanai et al. (US 4,868,183) and Uchida et al. (US 5,215,999) Should be Withdrawn

Claims 2, 4-6, 8-9, 11, 13-14, 16-19, 21-22, 24, 31, 33, 35-36, and 73-76 were rejected under 35 USC §103(a) as unpatentable over CA 2,068,366 in view of Kanai et al. (US 4,868,183) and Uchida et al. (US 5,215,999). Applicants respectfully disagree for the reasons that follow. According to the Office Action,

“CA 2,068,366 teaches a taste-masked free-slowing powder including microcapsules having a particle size of 300 microns or less that includes a core element including at least one pharmaceutically active ingredient . . . CA 2,068,366 does not teach the second coating layer is comprises of a water soluble and/or water swellable film forming polymer and an anti-grit agent such as polyethylene oxide or polyethylene glycol or the claimed ratios. It is for this reason Kanai et al. and Uchida et al. are added as secondary references. . . . Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element on the invention has been fairly suggested by the cited reference.”

See Pages 7-11 of the Office Action.

Applicants again respectfully disagree. As discussed in the above rejection, the current claims relate to coated particles, not to a coated tablet. Also as discussed above, both Kanai et al. and Uchida et al. teach the use of the recited coatings in tablet coatings, not particle coatings as recited in the pending claims. Neither, Kanai et al. and Uchida et al. disclose the current claimed coated particles or methods of manufacturing coated particles.

Further, as discussed above, in the interests of furthering this application to allowance, have amended independent claims 8, 31, 73, and 75 to now recite that the second coating layer does not retard the dissolution of the active ingredient. Thus, such a second layer recited in the pending claims is not recited, or suggested, in CA 2,068,366. In fact, CA 2,068,366 relates to microparticles having a “reduced dissolution profile.” See, e.g., claim 1 of CA 2,068,366.

Accordingly, one of ordinary skill in the art would not have been motivated by CA 2,068,366 replace the hydrophobic layer of CA 2,068,366, which provide the sought after “reduced dissolution profile” with the second layer of the present invention, which does not retard the dissolution of the active ingredient.

Further, as with Cherukuri et al., CA 2,068,366 also fails to teach or suggest the unexpected results found by the Applicants discussed above.

Accordingly, Applicants assert that the presently claimed invention would not have been obvious to a person of ordinary skill in the art at the time of the claims invention was made in light of these references. Thus, Applicants respectfully request that this rejection under 35 USC 103(a) be withdrawn.

Conclusion

For the foregoing reasons, the present application is in condition for allowance. Accordingly, favorable reconsideration of the presently presented claims in light of the above remarks and an early Notice of Allowance are courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned Attorney at the below-listed number.

The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/MCP0231USNP/WEM.

Respectfully submitted,

By: /William E. McGowan/
William E. McGowan
(Attorney for Applicants)
Reg. No. 39,301

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2197